

REMARKS

Claims 1-185 are pending in the present application. Claims 16-31, 56-81, 97-112, 137-162, 166, 167 and 172-185 have been withdrawn from consideration. Claims 1-15, 32-55, 82-96, 113-136, 163-165 and 168-171 stand rejected. Accordingly, claims 1-15, 32-55, 82-96, 113-136, 163-165 and 168-171 are currently under consideration. No new matter is added by this amendment.

With respect to all amendments and cancelled claims, Applicant has not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicant reserves the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional application.

Telephonic Interview

Applicant wishes to thank Examiner Spiegler for the courtesy of the March 11, 2004, telephonic interview conducted with Applicant and the undersigned, during which the obviousness-type double patenting rejection was discussed.

Supplemental Information Disclosure Statement

In an abundance of caution, Applicant has submitted herewith a supplemental Information Disclosure Statement and Form 1449, citing U.S. Patents Nos. 6,692,918 ("the '918 patent") and 6,686,156 ("the '156 patent"), both of which recently issued. Applicant previously brought the applications which resulted in the '918 and '156 patents (U.S. Applications Nos. 09/990,531 and 09/893,191, respectively) to the Examiner's attention in the Amendment filed August 14, 2003.

Obviousness-type double Patenting

Claims 1-15, 32-55, 82-96, 113-136, 163-165, 168-171 stand rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims

1-116 of U.S. Patent No. 6,251,639 ("the '639 patent"), in view of Soderlund et al. (U.S. Patent No. 6,013,431, "the Soderlund patent"). Applicant respectfully traverses this ground for rejection.

Applicant respectfully submits that the instant claimed invention and the claims of U.S. Patent No. 6,251,639 ("the '639 patent") are patentably distinct. The instant claimed invention operates by a different mechanism than the methods claimed in the '639 patent, and these differences are reflected in the language of the claims.

In accordance with the instant claims, the amplification (*e.g.*, the repeated primer extension) is possible because the primer extension product (the 3' DNA portion of the primer plus the nucleotides added by the polymerase) dissociates from the template following cleavage of the RNA portion (see claim 1, step (c) of the instant claims). This dissociation frees both the composite primer hybridization site and the portion of the template being amplified for another round of hybridization/primer extension/cleavage (*i.e.*, amplification). Strand displacement is not required because the primer extension product has dissociated from the template.

In contrast, the '639 patent claims methods by which amplification (*e.g.*, the repeated primer extension) is made possible by strand displacement of the previous primer extension product by strand displacement activity of the DNA polymerase (see step (d) of claims 1 and 2 of the '639 patent). In the methods of the '639 patent, the primer extension product remains hybridized to the template after cleavage of the RNA portion of the composite primer. A new composite primer can then hybridize (because the cleaved RNA portion of the composite primer dissociates from the template), but primer extension cannot take place unless the primer extension product from the previous round of amplification is displaced by strand displacement.

The January 12, 2004, Office Action suggests that Examiner has taken the position that the invention claimed in the '639 patent and the instant claimed invention operate in the same way. In particular, the Examiner states that in the instant claimed invention "the extended cleaved primer extension product is dissociated such that another composite primer hybridizes to the template and repeats primer extension by strand displacement." Office Action at page 6. As discussed above, the instant invention does not require strand displacement (see page 40, lines 3-7, and Example 6 at

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page 131-132 of the instant specification). Instead, the instant invention relies on the properties of the composite primer itself to dislocate the primer extension product off the template; the primer is designed to prime an extension product that dissociates from the template after cleavage of the RNA portion of the composite primer (and thus strand displacement is not required for the synthesis of a new copy of the template). In contrast, as recited in the claims of the '639 patent, the invention of the '639 patent utilizes strand displacement to dislocate the previous primer extension off the template (thus allowing the synthesis of another primer extension product).

Applicant further notes that the Examiner has not demonstrated that the claims of the '639 patent teach or suggest generation of primer extension product of a size that when the RNA is cleaved the cleaved primer extension product dissociates from the target polynucleotide. Nor has the Examiner demonstrated a suggestion or motivation to modify the teaching of the claims of the '639 patent, such that the requirement repeated primer extension by strand displacement is modified or deleted. The Soderlund patent does not remedy this deficit. Accordingly, Applicant respectfully submits that the pending claims are patentably distinct with respect to claims 1-116 of the '639 patent. Withdrawal of this rejection is respectfully requested.


CONCLUSION

Applicant has, by way of the remarks presented herein, made a sincere effort to overcome rejections and address all issues that were raised in the outstanding Office Action. Accordingly, reconsideration and allowance of the pending claims are respectfully requested. If it is determined that a telephone conversation would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the unlikely event that the transmittal form is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 492692000300.

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Respectfully submitted,

By 

Nicholas Buffinger
Registration No.: 39,124
MORRISON & FOERSTER LLP
755 Page Mill Road
Palo Alto, California 94304
650-813-5816
(650) 494-0792
Attorneys for Applicant